

# Training the Mozambican Pharmacy Department on the Use of Pharmadex

July 2014



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July 2014



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## About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

## Recommended Citation

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## Key Words

Pharmadex, Mozambique, medicines registration

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## ACRONYMS AND ABBREVIATIONS

CTTF	Technical Committee for Therapeutics and Pharmaceuticals
MSH	Management Sciences for Health
NMRA	National Medicines Regulatory Authority
PD	Pharmacy Department
SIAMED	model system for computerized-assisted drug registration
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
TWG	technical working group
WHO	World Health Organization

## **ACKNOWLEDGMENTS**

We express our gratitude to the Pharmacy Department within the Ministry of Health for making this training possible. In particular, we would like to acknowledge Dr. Sultana, the Head of the Registration Department, as well as the entire registration staff for their time, commitment, and willingness to learn how to use Pharmadex.

We acknowledge the administration and staff of SIAPS Mozambique for the logistical and administrative support in preparation for and implementation of this training.





## **BACKGROUND**

Health products regulation consists of all the processes involved in the pre-marketing evaluation, marketing authorization, and post-marketing surveillance of medicines, vaccines/biologics, medical devices, and other health products to ensure compliance with established standards of product quality, safety, and effectiveness. National medicines regulatory authorities (NMRAs) are faced with challenges in improving their regulatory processes to achieve greater efficiency, ensure transparency, and facilitate communication of regulatory information. Despite several efforts to computerize medicines registration in developing countries, many countries are still confronted with the limitations of the tool they currently use, which may include manual processes. An electronic tool for the entire regulatory process including registration, licensing, inspection, quality control, and pharmacovigilance, is needed.

In 2012, the USAID-funded Systems for Improved Access to Pharmaceutical Services (SIAPS) Program, implemented by Management Sciences for Health (MSH), conducted a comprehensive assessment of the regulatory system in Mozambique and addressed the challenges of the current information system in use at the Pharmacy Department (PD) for medicine registration and other regulatory functions. According to the report, all processes and documents for medicines registration are managed manually in the current system, and it is recommended that an online computerized information management system be used to handle the registration process, along with other regulatory functions. An online system can significantly improve the efficiency of registration and reduce the backlog by tracking the application process, enhancing communications, and improving document management.

Following the regulatory assessment, SIAPS was asked in 2013 to review the information system and related technical assistance needs of the PD for product registration, licensing and inspection, pharmacovigilance, and quality assurance. In addition, a system analysis was performed to define data elements and identify an appropriate tool that is compatible with local technology and capacity. Based on the needs of the Mozambican PD, Pharmadex was chosen as the most appropriate electronic tool for the management of Mozambique's regulatory systems information.

## **GOAL AND OBJECTIVES OF THE TRAINING**

### **Goal**

The goal of the training was to implement Pharmadex in the PD with the aim of ensuring that the department had the necessary skills, knowledge, and technical support to effectively use and sustain it. Implementation involved adapting the tool to agreed-upon data elements, procuring the required hardware and/or software, identifying in-country IT support and maintenance, installing the program(s), finalizing the software, training users, and preparing for launch of the system.

### **Specific Objectives**

- Meet with members of the PD and gather any additional information regarding customizations/changes that need to be made to Pharmadex to better align with the Mozambican context
- Demonstrate Pharmadex and identify and finalize requirements and functionality
  - Validate processes flows
  - Validate user profiles
  - Validate legacy data (i.e., data migration)
- Train PD staff on how to use the tool
- Define reports for Pharmadex
- Develop a timeline for go-live, identifying the following:
  - Server/hosting
  - Local resource for IT support
  - Bugs (in the system)/change request process and methodology

## GENERAL OVERVIEW OF TRAINING PROCEEDINGS

Overall, Pharmadex was well received and met most of the PD's needs. Some customizations will need to be done, however (annex F). Although the registration staff seemed enthusiastic about Pharmadex, attendance varied during the training, as each day, there were different people (and numbers of people) who attended. Also, participants came and went as they pleased and very few stayed for the whole day all three days. Although in general, the PD seemed eager to use the tool, it was clear that it was not a priority, and neither was the training. We never started on time because of other meetings the PD had scheduled. During the last day's debrief with the entire PD, during which we demonstrated Pharmadex to Felicidade Sebastiao, the Director of the Pharmacy Department, she seemed uninterested in the tool, citing that they had previously used something similar (i.e., WHO's SIAMED) to no avail. She appeared only to meet with us as a formality, not necessarily to learn more about the tool or what it was capable of doing. For Pharmadex to be successful in Mozambique, it is essential that she support its use as she reports directly to the Ministry of Health, and thus is our strongest advocate.

There were some concerns about Pharmadex being a completely online tool as Internet connectivity is limited and inconsistent not only in the PD, but in the entire country. Thus, it was suggested for the time being, that Pharmadex could be hosted on a local area network connection, with the limitation that later on, external applicants would be unable to register themselves and access the website. Until the PD can establish reliable Internet connectivity, Pharmadex will not be used to its maximum capacity. In addition, there is some concern regarding the sustainability of Pharmadex in Mozambique post-training as there is no one from the local SIAPS team who is familiar enough with the tool to troubleshoot it, ensure its continued use, answer questions, and liaise with HQ.

The entire training was conducted in English without the aid of a Portuguese translator. Although the Pharmadex labels were translated into Portuguese (via Google translator), the participants felt more comfortable using the tool in English as the Portuguese translations were very poor. None of the participants were fluent in English, and their understanding of the language varied from person to person. Needless to say, there were some concepts that were lost in translation. The PD's eagerness to use and better understand the tool largely depends on having all of the Pharmadex fields properly translated into Portuguese, which is one of the first tasks that must be completed (annex A has a complete list of follow-up activities planned).

Surprisingly, we did not meet with USAID after the training, which would have been helpful to show them the progress we made with Pharmadex and to solicit their continued support for the project.

## DETAILED SUMMARY OF TRAINING SESSIONS

### Methods of Presentation

Pharmadex training took place over the course of three days (July 29-31, 2014) following a brief introduction of the tool the day before (July 28, 2014) and a debrief at the end (August 1, 2014). As much as possible, we tried to stick with the agenda outlined in annex B, but there were unforeseen delays, and some rescheduling and rearranging was necessary.

During the morning sessions, participants watched as Utkarsh (UT) went through the Pharmadex system via an overhead projector as Louis answered any technical questions that arose. In the afternoon, participants utilized the tool themselves on their personal laptops using fictional data to generate information. Each day ended with a question and answer session as well as a recap of the previous days' activities. All trainings were conducted in English.

### ***Day 1 – July 28, 2014***

No training took place this day because of the Eid Celebration. Instead, a brief overview of Pharmadex (annex D) was given to the entire PD.

### ***Day 2 – July 29, 2014***

Training began at 8 a.m. with 12 members from the PD (annex C). About an hour into the training, nine people suddenly had to leave for another meeting. We had to delay the training for another hour until they returned, and even then, not everyone came back. In the end, only six people stayed for the whole training, including 1 essential person from the Registration Department.

The training consisted of a demonstration of Pharmadex projected onto a screen, which included an overview of the system, administrative functions, an explanation of different users, and registration of users, companies, and products. Afterwards, there was an interactive session in which participants could play with the system themselves by registering as users and submitting product applications. Internet connectivity was an issue and thus, all computers were hooked up to another computer which functioned as the local server.

There were some technical issues encountered during the training. For instance, it was very clear that Pharmadex would not work on any web browser other than Google Chrome. None of the participants had Chrome installed on their personal computers and the system kept crashing when they used Firefox or Internet Explorer. Thus, Chrome had to be downloaded and installed on each computer before proceeding. In addition, there were some problems when users tried to register themselves. The Gmail account that is used to automatically generate and email users their passwords became blocked. It did not recognize the Mozambican IP address and thought it was spam. Thus, user names and passwords had to be personally created for each participant. Once these issues were resolved, participants were able to continue using the system without any other problems.

### ***Day 3 – July 30, 2014***

Training began at 8 a.m. with eight people. We did a brief recap of the first day's activities and then continued with an explanation of how applications are processed within the system by the different users (receiver, moderator, evaluator, head, etc.). In the afternoon, participants processed an entire product application themselves, from submitting an application to registering the product.

No major problems were encountered during the registration process or logging on and using the tool as different users. Everyone was able to successfully register a product from start to finish. However, some modifications to the types of users are necessary, as in Mozambique, the moderator and evaluator are the same person and will need to perform two different functions as one user.

### ***Day 4 – July 31, 2014***

Because of another PD meeting, training did not begin until 9 a.m. with nine people. We reviewed the second day's activities, and participants practiced again how to process an application from start to finish. In the afternoon, we discussed amendments and renewals and gathered information about the post-registration process. No major problems were encountered.

### ***Day 5 – August 1, 2014***

During this last day, no formal training occurred, and instead, we discussed next steps in the implementation process (annex A). In addition to having a proper Portuguese translation of Pharmadex, a critical next step to ensure its success is the formation of a technical working group (TWG). The TWG will be comprised of members of the PD and will be responsible for coordinating, testing, and collecting feedback from the registration staff regarding Pharmadex; coordinating translation of the system labels and acronyms into correct Portuguese; designating someone who will touch base with the SIAPS HQ Pharmadex team every month for 30 minutes to discuss progress and preparedness of the tool; and coordinating verification of all the PD's needs, including when the tool will be ready for a national launch.

We also gathered some documents that will need to be added to Pharmadex including updated registration forms for new, generic, and recognized products; an acknowledgement letter; a pharmaceutical review report; a clinical review report; a recommendation letter from the Technical Committee for Therapeutics and Pharmaceuticals (CTTF); a letter to the Ministry of Health for approval of a drug; and a registration certificate.

Finally, we met with the entire PD, including the Director, Felicidade Sebastiao, to debrief them on the week's activities (annex E) and discuss next steps (annex A).

## ANNEX A. POST-TRAINING IMPLEMENTATION PLAN

Action	Deadline	Person responsible
Deploy system used for training	First week of August 2014	UT
Data migration of registered products from excel database	Second week of August 2014	UT
Translation of labels from English to Portuguese	Third week of August 2014	PD
Implement registration feedback collected during mission	Continuous	UT, Louis
Provide support and answer questions about the system	Continuous	UT, Louis
Gather feedback from the system from technical working group	Last week of September 2014	PD
Implement feedback into the system	Last week of October 2014	UT, Louis
Testing and PD acceptance of the tool	November 2014	PD
User manual	November 2014	Louis
Registration training	January 2015	PD, SIAPS
Pilot start	January 2015	PD, SIAPS
Include and train applicants in system	March 2015	PD, SIAPS
National launch	May 2015	PD, SIAPS
Include registration of other medical products in system	TBD	PD, SIAPS

## ANNEX B. TRAINING SCHEDULE

Pharmacy Department  
**Pharmadex** Training Workshop.  
**July 28 – 31, 2014**

<b>Time</b>	<b>Session/Activity</b>	<b>Responsibility</b>
<b>Day 1</b>		
<b>08:00-08:20</b>	Registration/Introduction	
<b>08:20-08:30</b>	Opening Remarks	<b>Dr. Sultana/Raouf</b>
<b>08:30-09:30</b>	Introduction to Pharmadex	<b>Utkarsh</b>
<b>09:30-10:30</b>	System Administration : Assigning Users and Changing Passwords	<b>Utkarsh</b>
<b>10:30-10:45</b>	<b>Tea Break</b>	<b>All</b>
<b>10:45-12:00</b>	Registration of Users and Applicants	<b>Utkarsh</b>
<b>12:00-13:00</b>	<b>Lunch</b>	<b>All</b>
<b>13:00-14:30</b>	Product Registration Module – Medicine Details and Manufacturing Activities	<b>Utkarsh</b>
<b>14:30-End</b>	Hands on exercise	<b>All</b>
<b>Day 2</b>		
<b>08:00-08:30</b>	<b>Recap of Day 1 activities</b>	<b>All</b>
<b>08:30-9:30</b>	Screening of Applications	<b>Utkarsh</b>
<b>10:00-10:30</b>	Processing/Review of Applications	<b>All</b>
<b>10:30-10:45</b>	<b>Tea Break</b>	<b>All</b>
<b>10:45-12:00</b>	Processing/Review of Applications (cont.)	<b>Utkarsh</b>
<b>12:00-13:00</b>	<b>Lunch</b>	<b>All</b>
<b>13:00-14:30</b>	Processing/Review of Applications (cont.)	<b>Utkarsh</b>
<b>14:30-End</b>	Hands on exercise	<b>All</b>
<b>Day 3</b>		
<b>08:00-08:30</b>	<b>Recap of Day 2 activities</b>	<b>All</b>
<b>08:30- 09:00</b>	Renewals	<b>Utkarsh</b>
<b>09:00-09:30</b>	Post-Approval Amendments	<b>Utkarsh</b>
<b>09:30-10:30</b>	Discussions	<b>All</b>
<b>10:30-10:45</b>	<b>Tea Break</b>	
<b>10:45-12:00</b>	Discussions (cont.)	<b>All</b>
<b>12:00-13:00</b>	<b>Lunch</b>	
<b>13:00-End</b>	Next Step	<b>All</b>

## ANNEX C. ATTENDANCE LIST

No.	Name	Designation	Days Present
<b>Facilitators</b>			
1	Utkarsh Srivastava	SIAPS HQ MIS Senior Advisor	7/28/14 – 8/1/14
2	Louis An	SIAPS HQ Technical Associate	7/28/14 – 8/1/14
3	Neusa Bay	SIAPS Mozambique Technical Advisor	7/28/14
4	Abdel Raouf Qawwas	SIAPS Mozambique Country Director	7/28 – 7/29/14
<b>Participants</b>			
1	Joaquim Tomas	Registration Biologist	7/28 – 8/1/14
2	Virgilio Fernando	Legal advisor	7/28/14, 8/1/14
3	Gilberto Pedro Manual	Inspection Pharmacist	7/28 - 7/29/14, 8/1/14
4	Dulce Tholande	Pharmacist	7/28/14, 8/1/14
5	Luisa Namburete	Pharmacovigilance Pharmacist	7/28/14, 8/1/14
6	Nercia Larya	Pharmacist	7/28/14, 8/1/14
7	Benedito Nhaguila	Registration Pharmacist	7/28 - 7/29/14, 7/31 -8/1/14
8	Nazalia L. Macude	Registration Pharmacist	7/28 – 7/30/14, 8/1/14
9	Celia F. Matavela	Registration Pharmacist	7/28 – 8/1/14
10	Cassiano Carlos Joao	Registration Pharmacist	7/28 – 8/1/14
11	Carla Djamis	Legal advisor	7/28/14, 8/1/14
12	Velma P.P. Capote	Registration Pharmacist	7/28 – 8/1/14
13	Cidalia Vilancules	Registration Biologist	7/28 – 8/1/14
14	Sultana Razaco	Head of registration department	7/29 – 8/1/14
15	Josina Jose Jad	Registration Pharmacist	7/29 – 8/1/14
16	Merana Mussa	Pharmacovigilance Pharmacist	7/29/14, 8/1/14
17	Rosila Khan	Registration Pharmacist	7/29/14, 7/31/14, 8/1/14
18	Felicidade Sebastiao	Director of Pharmacy Department	8/1/14



## ANNEX D. PHARMADEX OVERVIEW PRESENTATION

# Regulatory Information Management System (PharmaDex)



Utkarsh Srivastava (UT)  
Louis An

### Overview

- Introduction To PharmaDex
- Benefits of Computer Assisted Drug Registration (PharmaDex)
- Modules of PharmaDex
- Registration Module
  - Features
  - Application Flow
  - Regulatory Board Processing
- Inspection Module
- Pre-requisites for Computer-Assisted Drug Registration
- Security
- Software Architecture



### PharmaDex

PharmaDex is a web-based integrated solution that streamlines management, dissemination, and sharing of regulatory information around

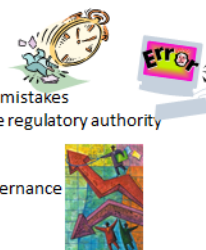
- Registration
- Inspection & post market surveillance

It promotes transparency, accountability, and good governance in health products regulation.



### Benefits of Computer Assisted Drug Registration

1. More time for professional work
2. Fewer imprecisions, oversights, and mistakes
3. Improved communication within the regulatory authority
4. Increased efficiency
5. Improved quality of work
6. Improve transparency and good governance



However, computerization alone is unable to replace proper regulations, qualified staff, and efficient work procedures and condition.



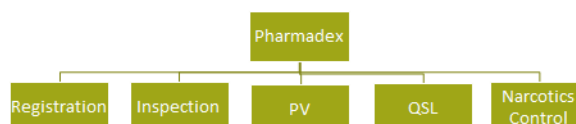
### Integrated Platform



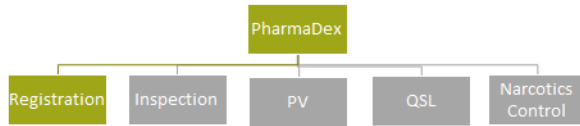
### Modules of PharmaDex

PharmaDex consist of following modules

- Product and Company Registration
- Inspection (Pre and Post market Inspection)
- Pharmacovigilance (PV)
- Quality Surveillance Laboratory (QSL)
- Narcotics Control
- Administration



## Products and Company Registration



## Drug and Applicant Registration

- Online application for registering products and pharmaceutical establishments
- Records and organizes information on suppliers and medicines from their registration applications
- Categorizes registrants according to the different stages of the registration process
- Records the progress of the applications
- Provides functionality to assign reviewers, enter reviewers comments and track the progress of reviewers
- Provides functionality to upload documents, add comments and send emails
- Produces analysis and comparison reports on products and suppliers registered in the country
- Creates renewal invoices and track there status
- Provides functionality to report amendments



## User and Roles Types

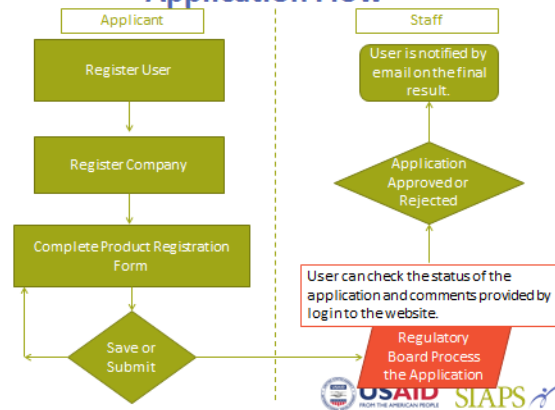
- Public User
- Applicants
- Pharmacy Department Staff

## Pharmacy Department Staff Roles

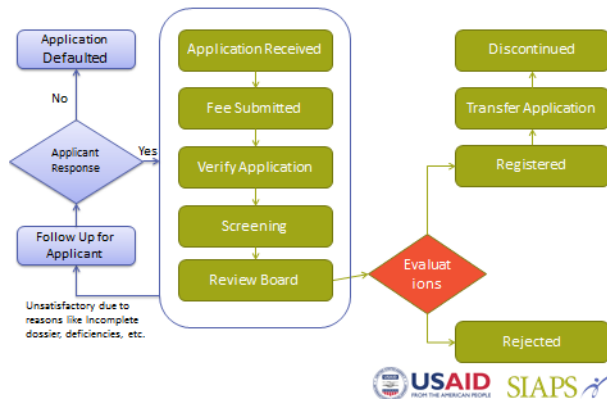
- Head
- Moderator
- Evaluators



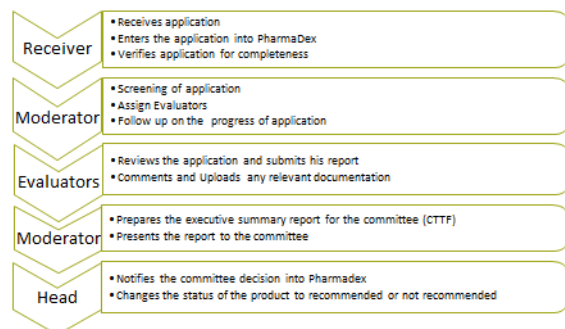
## Application Flow



## Processing Registration Applications



## Application Process Flow



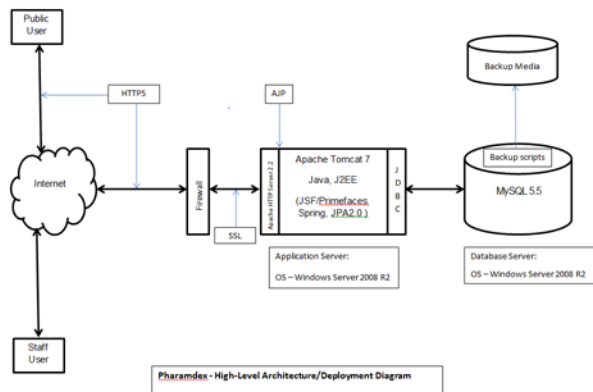
## Inspection

### Pre Market Inspection

- Inspection of drugs entering the country

### Post Market Inspection

- List of Health facilities
- Database of licensed dispensing physicians
- GMP inspection
- List of Pharmacists/medical practitioners/etc registered with the Councils
- List of wholesalers/distributors/importers/Exporters



## Security

Three levels of security are implemented in the system

- Encryption of data flowing back and forth between server and client using HTTPS.
- Authentication: Username and password based authentication of users to the website. Passwords are encrypted inside the database with the combination of username and password.
- Authorization: Role based access to menu items pages and functions.



### Pre-requisites for Computer-Assisted Drug Registration

- **Legislation and regulations** must support the work of the regulatory authority, rather than hindering it, either directly or indirectly.
- **Human Resources:** The NRA's scientific experts should be complemented by a suitable number of administrative staff, computer specialists, and legal experts.
- **Adequate Financing Mechanism:** The cost of computerization is marginal when compared to what governments are actually spending in the area of regulation and control.
- **Registration Fees:** Registration fees applied in most developing countries are too low to support the work of their regulatory authority, and sometimes too low for what the countries' markets could bear without having an adverse effect on access to pharmaceutical products.
- **Hardware:** At a minimum, there should be at least one computer dedicated exclusively to the core database of company and drug product information.

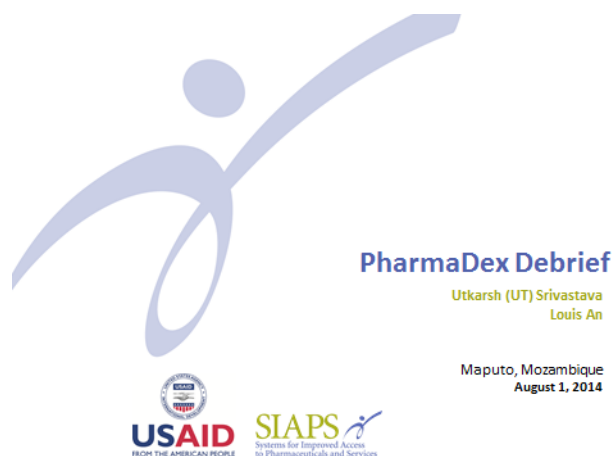


## Moving from a Manual to Computer-Assisted Drug Registration – Implementation Process

1. Secure Leadership Support
2. Review Enabling Legislation and Regulations
3. Identify Needs, Define Enabling Objectives, and Establish Priorities
4. Identify Funding and Support Requirements and Success
5. Appoint Technical Coordinator and Define Time Schedule
6. Review Forms, Procedures, and Correspondence
7. Update Forms and Certificates, as Required
8. Prepare Data and Decide How to Handle Data Entry
9. Train Staff in Software Systems and New Procedures
10. Begin Computerization
11. Operate and Maintain Computer-Assisted Drug Registration System



## ANNEX E. PHARMADEx DEBRIEF PRESENTATION



### Activities

- Demo of the Current Pharmadex with the SIAPS Team
- Activity planning for the pharmacy department with the SIAPS Team
- Introduction of web based Pharmadex
- Demonstration and Training of Pharmadex
- Demonstration of post-registration Amendments & Renewals
- Gathered customization list for Registration module
- Collect documents to implement and update the system



### Observations

- The web based tool satisfies the needs of Pharmacy Department registration staff with some further customizations
- Data migration from the Excel sheet needs to be done to have the list of currently registered products in the system
- Will need feedback from the registration staff for the translation of labels



### Major Changes

- Changes to the registration form
- Implementing WHO pharmacological classification data
- Creating the reviewers report submitted to the committee
- Creating the different report based on the country template
- Add new fields to the system
- Data migration



### Concerns

- Pharmadex not available in offline mode
- Overall technical sustainability of the system



### Documents Collected

- Updated registration forms: new, generic, recognized products
- Acknowledgement letter
- Pharmaceutical review report
- Clinical review report
- Recommendation letter from CTTF
- Ministry of Health letter for approval of drug
- Registration certificate



## Technical Working Group

PD staff nominated by the Pharmacy department with the following responsibilities

- Will coordinate testing and collecting the feedback from the registration staff
- Will coordinate translation of the system labels into Portuguese and currently used acronyms
- Will do touch base every month for 30 minutes to discuss the progress and preparedness of the tool
- Will coordinate verification of all the needs of pharmacy department and if the tool is ready for use.
- Assign a focal point in the taskforce to communicate with MSH Pharmadex team



## Next Steps

Activity	Deadline	Resource
Deploy the system used for the training	First week August	UT
Data Migration of registered products from the excel database	Second week August	UT
Translation of Labels from English to Portuguese	Third week August	PD
Implement the registration feedback collected during the mission	Continuous	UT, Louis
Provide support and answer questions about the system	Continuous	UT, Louis
Gather feedback for the system from the TWG	Last week September	PD



## Next Steps (Phase 2)

Activity	Deadline	Resource
Implementing the feedback into the system	Last week October	UT, Louis
Testing and PD acceptance of the tool	November	PD
User manual	November	Louis
Registration training	Jan	PD, MSH
Pilot start	Jan	PD, MSH
Include Applicants into the system and train applicants to submit registration using the system	March	PD, MSH
National Launch	May	PD, MSH
Include registration of other medical products in the system	TBD	PD, MSH



## Lessons Learned

- During development of Pharmadex we should be working more closely with the client
- We should give priority to developing functionalities that are more relevant to the country needs in comparison to complex functionality that might not be used in near future
- We need to manage expectations for the Regulatory board as the process for implementing Pharmadex requires few months
- We should not be dependent completely on SOP's for understanding the process as the practices in reality are some times different as compared to SOP's.
- We need to make clear distinction between Applicant and Manufacturing Site.



## Deliverables

- Trip Report
- Customizations List
- Requirements Documents
- Training report



## ANNEX F. PHARMADEX NOTES AND CUSTOMIZATIONS

### Notes

- PD receives about 10 applications per week
- Takes about 6-9 months processing time for applications
- Two levels of reviewing: PD review and clinical review by CTTF
- Currently Vilma and Nezalía are the persons responsible for entering data in the Excel database
- The registration fee for new medicines is \$700
- Internet connectivity is the major issue for the system
- Checklist received from the department is the application form used by applicants
- Recognized products are the list of products registered in Europe and Brazil except ARV, TB, and antimalarial drugs; these three types have to go through the complete registration process
- Renewals go through the same process as registration
- All the renewals are sent to CTTF for approval
- For amendments, 8000 Metical (~\$267) is charged for major changes and 1000 Metical (~\$33) for minor amendments
- Not all of the amendments are sent to CTTF

### Customizations

- Add formulary code to the medicine detail page
- Define market authorizing holder → the company that is responsible for selling the product in another country
- Add the two PD people who are mainly responsible for receiving the application (Josina and Sarina)
- Do the translation for shelf life
- Product list page dosage form translation
- Introduce a new field to capture the FNM (Formulary National Medicine) code
- Change “Process Number” to “Application Number”
- Implement screen lock after submit
- Dosage form and pharmacological classifications need to be translated into Portuguese in drop down menu
- Change subject of Pharmadex email (remove Namibia references)
- Introduce the ability to add INN instead of just selecting from the dropdown
- Confirmation message for applicant registration
- Replace list of countries where product is registered by a table with country name and registered number

- Collect soft copy and hard copy of the reports/PDFs/letters to be generated by the system
- Renewal of product notifications
- Mechanism to discard products
- Mechanism to edit submitted data
- Mechanism to alert user if product with same name is already registered by another applicant
- Implement the default date/time format in the system
- Insert payment information (bank name and date of payment)
- Applicant registration form: if no user is selected, then give an error message
- Include a functionality to cancel registration
- Include functionality to transfer application to others
- After a product is rejected, provide functionality to send the product for review so it can be registered after further processing if the product is approved

## ANNEX G. PHARMADEX TRAINING GROUP PHOTO

